IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
HATTIESBURG DIVISION

JAN HUGHES **PLAINTIFF**

v. **CIVIL ACTION NO. 2:08-CV-00079-KS-MTP**

BOSTON SCIENTIFIC CORPORATION **DEFENDANT**

MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

COMES NOW the Defendant, Boston Scientific Corporation (hereinafter "BSC"), by and through its attorneys of record, and submits this *Memorandum of Authorities in Support of its Motion for Summary Judgment* pursuant to Rule 7.2(D) of the UNIFORM DISTRICT COURT RULES. For the reasons set forth herein and in its *Motion for Summary Judgment*, BSC is entitled to judgment as a matter of law with regard to any and all claims asserted against it by Jan Hughes.

I. PROCEDURAL HISTORY

The Plaintiff filed her *Complaint* in the Circuit Court of Jones County, Mississippi on March 26, 2008, alleging that BSC negligently designed, manufactured, packaged, marketed and sold an unreasonably dangerous and/or defective medical device - specifically, a Hydro ThermAblator (hereinafter "HTA"). See *Complaint*, attached hereto as *Exhibit "A."* She further asserts that BSC is strictly liable under Mississippi's product liability statute and breached implied warranties of merchantability and fitness for a particular purpose. *Id.* Plaintiff Hughes seeks damages in the form of compensatory, as well as punitive, damages. *Id.* BSC promptly and properly removed the case to this Court and subsequently filed its *Answers and Defenses*, denying any and all liability for

the Plaintiff's alleged injuries. Discovery has commenced and it is clear, from the discovery already exchanged, that BSC is entitled to summary judgment as a matter of law.

II. UNDISPUTED MATERIAL FACTS

According to the *Complaint*, on October 25, 2006, the Plaintiff underwent outpatient treatment at the South Central Regional Medical Center (hereinafter "SCRMC") in Laurel, Mississippi for a condition known as menorrhagia.[1] *Exhibit "A"* at ¶¶ 5-7. The particular procedure, endometrial ablation, was performed on the Plaintiff with the utilization of the HTA by her gynecologist. *Id.* at ¶ 5. During the procedure, a probe is inserted into the Plaintiff's uterus for viewing of the uterus lining. See *HTA System User's Manual*, attached hereto as *Exhibit "B."* A seal is then formed around the cervix to prevent leakage and heated saline solution is then circulated throughout the uterus to remove its lining. *Id.* After a cooling process in which the saline solution is removed, the procedure is complete. *Id.*

One of the risks associated with this procedure is a potential for leakage of hot fluid, which may result in thermal injury to surrounding tissue. *Id.* The HTA system is equipped with a leakage detection system that will sound an alarm and automatically shut down the procedure if a leak is detected. *Id.* The risk of leakage and resulting thermal damage is fully and unambiguously explained in the HTA System User's Manual. *Id.;* see also *Deposition of Michael Weber, M.D.* at 46:10-13, attached hereto as *Exhibit "C."* The User's Manual was provided to the Plaintiff's gynecologist as well as to the Plaintiff herself prior to the procedure. *Exhibit "C"* at 31:5-18; see also *Deposition of Jan Hughes* at 13:17-24, attached hereto as *Exhibit "D."*

[1] Menorrhagia is the medical term referring to excessive or prolonged uterine bleeding.

During the Plaintiff's procedure, after heated saline solution was circulated into the uterus, a leak was detected and the procedure was properly suspended, as it was designed to do. *Exhibit "C"* at 39:8-40:4. Unfortunately, Ms. Hughes sustained scalding to the inner and outer walls of the vagina. *Id.* She subsequently filed the instant lawsuit against BSC, seeking damages for pain and suffering, mental anguish and embarrassment, emotional distress and past and future medical expenses. *Exhibit "A."* Count I of her *Complaint* seeks to impose strict liability upon BSC in accordance with Mississippi's product liability statute. *Id.* Specifically, the Plaintiff has alleged that

> a. The HTA deviated in a material way from BSC's manufacturing specifications and from otherwise identical units manufactured by BSC to the same manufacturing specifications;
> b. The HTA failed to contain adequate warnings and instructions; and
> c. BSC breached express warranties.

Id. She adds that these alleged defects rendered the HTA unreasonably dangerous and the unreasonably dangerous condition was the proximate cause of her injuries. *Id.* She also contends that BSC was negligent in the manufacture, design, labeling, marketing and selling of the HTA and that BSC's negligence was the proximate cause of her injuries. *Id.* Further, she alleges negligence on behalf of BSC in the hiring, training and supervision of its agents and representatives. *Id.* Finally, the Plaintiff asserts that BSC breached implied warranties of merchantability and fitness for a particular purpose. *Id.*

III. SUMMARY JUDGMENT STANDARD

Pursuant to Rule 56(b) of the FEDERAL RULES OF CIVIL PROCEDURE, "a party against whom relief is sought may move at any time . . . for summary judgment on all or part of the claim."

Summary judgment, in whole or in part, "shall be rendered if the pleadings, pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. PRO. 56(c). Issues of fact are material if they will make a difference in the outcome of the case. *Chio v. Plano Independent School District*, 260 F.3d 330, 341 (5th Cir. 2001) (citing *Colston v. Barnhart*, 146 F.3d 282, 284 (5th Cir. 1998)). To determine whether an issue of material fact is genuine, the Court must "decide whether 'the evidence is such that a reasonable jury could return a verdict for the non-moving party.'" *Id.* Where no reasonable jury could find for the non-movant, summary judgment is appropriate. See *Vulcan Material Co. v. City of Tehuacana*, 369 F.3d 882 (5th Cir. 2004)(citing *Gillis v. Louisiana*, 294 F.3d 755, 758 (5th Cir. 2002)). Based on the undisputed material facts of this case, the Plaintiff's claims are preempted by federal statute and therefore, BSC is entitled to judgment as a matter of law.

Moreover, the United States Supreme Court has held that the language of Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a sufficient showing to establish the existence of an essential element to that parties' case, and on which that party will bear the burden of proof at trial." *Celotex Corp. vs. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986); See also *Clark v. Commercial Credit Corp.*, 357 F. Supp. 2d 962 (5th Cir. 2005); *U.S. v. Southland Oil*, 339 F. Supp. 2d 764 (5th Cir. 2005). The party moving for summary judgment bears the initial responsibility of informing the Court of the basis for its motion and identifying those portions of the record in the case which it believes demonstrates the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. The moving party is not required to disprove the non-moving party's claims, but

rather, need only show that the party who bears the burden of proof has adduced no evidence to support an element essential to its case. *Teply v. Mobile Oil Corp.*, 859 F.2d 375, 379 (5th Cir. 1998) (citing *Celotex*, 477 U.S. at 322. As to issues on which the nonmoving party has the burden of proof, the nonmoving party must "make a showing sufficient to establish the existence of elements essential to his case." *Kerr-McGee Corp. v. Maranatha Faith Ctr., Inc.*, 873 So.2d 103, 107 (Miss. 2004) (citing *Cothern v. Vickers, Inc.*, 759 So.2d 1241, 145 (Miss. 2000)). In the instant case, the Plaintiff has also wholly failed to come forward with any evidence in any form that tends to establish the essential elements of her claims of negligence, strict liability, and breach of warranty. Accordingly, BSC is entitled to summary judgment as a matter of law with regard to those claims in the event that this Honorable Court does not find that the Plaintiff's claims are preempted by federal statute.

IV. ARGUMENT AND AUTHORITIES

The United States Supreme Court has unequivocally stated that the preemption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars state tort lawsuits challenging the safety or effectiveness of a Class III medical device given premarket approval (hereinafter "PMA") by the Food and Drug Administration (hereinafter "FDA"). Because the medical device which is the subject of the instant *Complaint* is (1) a Class III medical device and (2) has received premarket approval by the FDA, the Plaintiff's claims against BSC are preempted by federal law. Accordingly, BSC is entitled to judgment as a matter of law. Even if this Honorable Court finds that the Plaintiff's claims are not preempted by federal law, BSC is nonetheless entitled to summary judgment, as the Plaintiff has failed to establish the essential elements of her claims for negligence, strict liability and/or breach of warranty.

A. ***The Plaintiff's claims are preempted by federal statute.***

Section 360k(a) of the Medical Device Amendments provides:

> Except as provided in subsection (b) of this section,[2] no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a). In other words, the MDA expressly preempts only state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1006 (U.S. 2008). Therefore, to determine whether the Plaintiff's claims are preempted, we must first determine whether the Federal Government has established requirements applicable to BSC's HTA. *Id.* If so, we must then determine whether the Plaintiff's common law claims are based upon Mississippi requirements with respect to the device that are "different from, or in addition to" the federal ones, and that relate to safety and effectiveness. *Id.* Because both of these questions are answered in the affirmative in the instant case, the Plaintiff's claims are preempted by federal statute and BSC is entitled to summary judgment as a matter of law.

i. <u>The HTA is a Class III medical device and therefore, subject to premarket approval</u>.

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[2] The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption but has no application in the instant case. 21 U.S.C. §360k(b).

The MDA divides medical devices into three (3) classes, depending on the risks the devices present, and establishes various levels of governmental oversight for each class. *Id.*

> Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject . . . to "special controls" such as performance standards and postmarket surveillance measures [in addition to "general controls"]. The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators and pacemaker pulse generators[.] In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury."

Id. at 1003 (internal citations omitted) (citing, with regard to Class III medical devices, 21 U.S.C. §360c(a)(1)(C)(ii)). It cannot be disputed in the instant case that the subject device is a Class III medical device. See *Product Classification Database Search Results*, database maintained by the U.S. Food and Drug Administration, available at http://www.fda.gov and attached hereto as *Exhibit "E,"* last accessed 15 Jan 2009. Accordingly, the HTA is subject to federal requirements imposed upon all Class III medical devices.

Federal oversight of Class III medical devices is achieved by a requirement of premarket approval of the device by the FDA prior to distribution. Although there are some exceptions to the requirement of pre-market approval, such as devices which are "grandfathered in" or devices which are "substantially equivalent" to another device exempt from pre-market approval, such exceptions are not applicable to the subject HTA. See 21 U.S.C. §§ 360c(f)(1), 360e(b)(1),

360c(f)(1)(A). Premarket approval is a rigorous process which includes, *inter alia*, the submission of:

- full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the manufacturer;
- a full statement of the device's components, ingredients, and properties;
- a full statement of the principle or principles of operation;
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;
- samples or device components required by the FDA; and
- a specimen of the proposed labeling.

Riegel, 128 S.Ct. At 1003 (citing 21 U.S.C. § 360e(c)(1)). Even then, if the FDA is not satisfied with approval, the agency may refer the application to an outside panel, request additional data from the manufacturer. *Id.* (citing 21 CFR § 814.44(a) (2007); 21 U.S.C. § 360e(c)(1)(G)). The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" as determined by "weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* citing 21 U.S.C. §§ 360e(d); 360c(a)(2)(C)). Therefore, even where a device presents a great health risk, it may be approved where it offers great benefits in light of available alternatives.[3] *Id.*

Once a device is approved, the manufacturer is forbidden to make changes in design specifications, manufacturing process, labeling or any other attribute that would affect the safety or effectiveness of the device without FDA approval. *Id.* (citing 21 U.S.C. §§ 360e(d)(6)(A)(i)). Further, the manufacturer is under a continuing duty to report the results of new studies or

[3] The FDA could also, of course, deny approval, condition approval on adherance to performance standards or compliance with other requirements or restrict the sale or distribution of the device. *Id.* (citing 21 CFR §§ 861.1(b)(3), 814.82 and 21 U.S.C. § 360j(e)(1)).

investigations and adverse events possibly resulting from use of or malfunctioning of the device. *Id.* (citing 21 U.S.C. § 360i; 21 CFR §§ 814.84 (b)(2), 803.50(a)). The FDA has the authority to withdraw approval and is, in fact, required to withdraw approval where the device is determined to be unsafe or ineffective under its labeling conditions. *Id.* (citing 21 U.S.C. §§ 360e(e)(1), 360h(e)).

It cannot be disputed that the HTA has received and continues to maintain its PMA. Because premarket approval is a federal requirement applicable to BSC's HTA, this Honorable Court can now turn to the second tier of the preemption analysis - whether the Plaintiff's common-law claims rely upon a requirement of Mississippi law that is different from or in addition to the federal requirements and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device. *Riegel*, 128 S.Ct. at 1007 (citing 21 U.S.C. § 360k(a)).

ii. <u>The Plaintiff's common law claims are based upon Mississippi requirements with respect to the device that are different from, or in addition to those required under federal law and that relate to safety and effectiveness.</u>

The Plaintiff's claims - strict liability, negligence and breach of warranty - clearly relate to and revolve around the safety and effectiveness of the subject device. *Id.* Therefore, the critical issue is whether Mississippi's tort duties constitute "requirements" that are different from or in addition to federal ones. *Id.* Because the United States Supreme Court has unambiguously stated that "common-law actions for negligence and strict liability do impose 'requirements ,'" such claims are preempted by federal requirements specific to the HTA to the extent that they are different from or in addition to the federal MDA requirements. *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) (opinion of O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas,

J.); *Medtronic, Inc.*, 518 U.S. at 503-505, (opinion of Breyer, J.)); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

Finally then, with respect to whether such requirements are "different from" or "in addition to" federal MDA requirements, it is clear that any standards that could be imposed upon a manufacturer by a jury under theories of strict liability, negligence or breach of warranty would be "in addition" to and/or "different from" the standards imposed by the federal government when the federal standards have been met by the manufacturer. *Reigel* , 128 S.Ct. 999. In other words,

> [s]tate tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law [that requires a manufacturer's device to be safer]. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.

Id. at 1008. The only claims that would therefore survive preemption are claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA. *Gomez v. St. Jude Medical Daig Division Inc.*, 442 F.3d 919 (5th Cir. 2006). Because the Plaintiff has not asserted such a claim, as discussed *infra*, or because, alternatively, the Plaintiff has failed to establish the essential elements of such a claim, also discussed *infra*, none of the Plaintiff's claims survive the MDA's preemption clause and BSC is therefore entitled to summary judgment as a matter of law.

On February 20, 2008, the United States Supreme Court handed down its decision in the case of *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999. In *Riegel*, at issue was a cardiac balloon catheter marketed and sold by Medtronic. *Id.* at 1001. As is the HTA in the instant case, the catheter in *Reigel* was a Class III medical device that received premarket approval from the FDA under the MDA. *Id.* at 1005. The facts in *Reigel* are strikingly similar to those of the instant case. In *Reigel*,

the Plaintiffs filed a product liability suit against the manufacturer of a cardiac balloon catheter, Medtronic, after a catheter ruptured in Reigel's coronary artery during surgery. *Id.* at 1001. Similar to the instant Plaintiff's claim, the *Reigel* plaintiffs filed suit against Medtronic alleging strict liability, breach of warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, manufacture and sale of the catheter. *Id.* The *Reigel* trial court held that the MDA pre-empted these claims, and the United States Court of Appeals for the Second Circuit affirmed. *Id.* Certiorari was granted to the *Reigel* plaintiffs and the United States Supreme Court affirmed. *Id.* at 1011. In reaching its decision, the Court held that the MDA's express preemption clause bars state law claims challenging the safety and effectiveness of a Class III medical device that has received premarket approval from the FDA. *Id.* Further, the Court explained that the preemption clause is triggered where (1) the FDA has established regulations or other specific federal requirements applicable to the device at issue and (2) the claims at issue require adherence to requirements different from or in addition to the FDA's device-specific requirements. *Id.* at 1006. As stated above, the facts of the instant case parallel closely to those in *Reigel* and the instant Plaintiff asserts essentially the same theories of liability as did the *Reigel* plaintiffs. As such, Plaintiff Hughes's claims are likewise pre-empted and BSC is entitled to judgment as a matter of law.

Decisions of Mississippi courts, as well as those of the Fifth Circuit, are in accord with the *Reigel* opinion. Even before the Supreme Court's decision in *Reigel*, Mississippi law recognized federal preemption in medical device cases. In *Rutland v. Mentor Corp.*, 1994 WL 454741 (Miss. Cir. 1994), the plaintiff underwent a procedure for the installation of a penile prosthesis and subsequently experienced an infection which resulted in the removal of the prosthesis. *Id.* at 1.

Plaintiff subsequently filed suit against Mentor, the manufacturer of the prosthesis, alleging strict liability, negligence, and breach of warranty. *Id.* The Circuit Court of the First Judicial District of Harrison County, Mississippi found that because the prosthetic device was a Class III device with PMA, the plaintiff's claims were preempted by 21 U.S.C. Section 360k. *Id.* at 2. As a result, the Court granted summary judgment in favor of Mentor. *Id.* at 4; *see also Gomez*, 442 F.3d 919 (holding that patient's defective design, failure -to-warn, failure-to-train and breach of implied and express warranty claims were preempted but manufacturing defect claims were not, to the extent that patient alleged that the device was defectively manufacture because it did not comply with FDA specifications); *Hearn v. Advanced Bionics Corp.*, 2008 WL 3896431 (S.D. Miss.) (acknowledging *Reigel*, 128 S.Ct. 999); *Betterton v. Evans*, 351 F.Supp.2d 529 (N.D.Miss 2004) (holding that state law tort claims of strict liability, negligence and breach of warranties were preempted where pacemaker system and components were approved through the Product Development Protocol as provided in 21 U.S.C. § 360e(f)(3)(B)(I)-(viii)); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (holding that state common law products liability claims, for manufacturer's breach of duty in connection with its design, labeling and manufacture of pacemaker which had already been subject to rigorous premarket approval were preempted by MDA).

B. ***The Plaintiff has failed to establish the essential elements of her claims.***

Alternatively, if this Honorable Court should find that any of the Plaintiff's claims are not preempted by federal law, BSC is nonetheless entitled to summary judgment as a matter of law as she has not established the essential elements of her strict liability, negligence or breach of warranty claims.

i. Strict Liability

Mississippi's product liability statute provides that for a manufacturer of a product to be liable for damages caused by a product, the claimant must "prove by the preponderance of the evidence that at the time the product left control of the manufacturer . . .

> (1) The product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications,
>
> (2) the product was defective because it failed to contain adequate warnings or instructions,
>
> (3) the product was designed in a defective manner, or
>
> (4) the product breached an express warranty or failed to conform to the other express factual representations upon which the claimant justifiably relied in electing to use the product;

and the defective condition rendered the product unreasonably dangerous and . . . proximately caused the damages for which recovery is sought." Miss. Code Ann § 11-1-63(a). Therefore, essential to every claim for strict products liability is a showing that a defect in the product rendered the product unreasonably dangerous.

First, the Plaintiff has not, by any stretch of the imagination, established that the HTA was defective in any way. The HTA performed exactly as designed. At the first sign of leakage, the device sounded an alarm and automatically ceased the ablation process. *Exhibit "C"* at 39:8-40:4. Furthermore, the Plaintiff has not tested or otherwise evaluated the subject device for defects and therefore, cannot genuinely dispute that the device is not defective. Second, the Plaintiff absolutely has not established (and cannot in the future establish) that a defect in the product (which doesn't actually exist) rendered the HTA *unreasonably dangerous*.

The Mississippi Supreme Court has stated, with regard to prescription drugs, that some

products, although not absolutely safe, are not *unreasonably* dangerous. *Bennett v. Madakasira*, 821 So.3d 794, 809 (Miss. 2002) (citing Rest. 2d Torts §402, Comment k).

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attending with a known but apparently reasonable risk.

Id. (emphasis in original). The Fifth Circuit has added that accordingly, liability should only be imposed when the drug is not properly prepared, properly marketed or accompanied by proper warnings. *Id.* (citing *Swazy v. McNeil Laboratories*, 807 F.2d 464, 468 (5th Cir. (Miss.) 1987)). The same is true with regard to medical devices, especially with regard to Class III medical devices. "Inherent in a strict liability claim is the contention that the product is in a defective state [and] unreasonable to users. However, Class III medical devices by their very nature present a potentially "unreasonable risk of illness or injury," according to 21 U.S.C. § 360, and"the FDA has made a policy decision that Class III devices, if properly regulated and followed are worth the risk. *Rutland v. Mentor Corporation*, not reported in So.2d, 1994 WL 454741 (Miss.Cir.) (citing *King c. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993)). Therefore, the Plaintiff cannot, through a cost/benefit analysis, establish that the HTA is *unreasonably* dangerous. With regard to her claim that BSC breached an express warranty, the Plaintiff has not established that the product breached an express warranty, created by an affirmation of fact or promise, description or sample or model of the product, which is made a part of the basis of the bargain. MISS. CODE ANN. § 75-2-313. Accordingly, the Plaintiff's strict liability claim against BSC must be dismissed as a matter of law.

ii. Breach of Express and Implied Warranties

Implicit in every contract is a warranty that the goods are merchantable - in that they are fit for the ordinary purpose for which such goods are used, pass without objection in the trade under the contract description and conform to the promises or affirmations of fact made on the container or label, if any. MISS. CODE ANN. § 75-2-314. To recover for breach of implied warranty of merchantability, the plaintiff must establish that the defect was present when the product left the Defendant's control and that the defect proximately caused the plaintiff's damages. *CEF Enterprises Inc. v. Betts*, 838 So.2d 999 (Ct. App. Miss. 2003). As previously discussed, the Plaintiff has failed to establish that the HTA was at all defective in any way. As such, her claim for breach of implied warranty of merchantability must also fail as a matter of law.

Implied warranties of fitness for a particular purpose are created where the seller, at the time of contracting, has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods. MISS. CODE ANN. § 75-2-315. To recover under for breach of a warranty of fitness for a particular purpose, the plaintiff must prove that the seller, at the time of contracting, had reason to know the particular purpose for which the goods were required. *Lacy v. Morrison*, 906 So.3d 126 (Ct. App. Miss. 2004). Under Mississippi law, the warranty for fitness for a particular purpose does not apply where the plaintiff did not purchase the product from the defendant, as the plaintiffs could never then have relied on the skill or knowledge of the defendant's representative in picking the product, but rather, purchased or encountered the product through a third person. *Austin v. Will-Burt Co.*, 232 F.Supp. 682, 688 (N.D. Miss. 2002) (citing *Albriton v. Coleman Co.*, 813 F.Supp. 450, 455 (S.D. Miss. 1992)). Because the Plaintiff in the instant case did not purchase the HTA from BSC,

her claim for breach of warranty of fitness for a particular purpose cannot be maintained as well.

iii. Negligence

To maintain a claim for common law negligence, the Plaintiff must prove that the Defendant breached a duty owed to them and that the breach subsequently and proximately caused her injuries. *Paz v. Brush Engineered Materials, Inc.*, 949 So.2d 1 (Miss. 2007) (quoting *Miss. Dept. Of Mental Health v. Hall*, 936 So.2d 917, 922 (Miss. 2006). Duty and a breach of that duty are essential to a finding of negligence and must be demonstrated before any other element. *Brown v. J.J. Ferguson Sand & Gravel Co.*, 858 So.2d 129, 131 (Miss. 2003) (quoting *Strantz*, 652 So.2d at 742). The Plaintiffs in the instant case clearly have not established, nor can they establish, that the Defendant breached any duty owed to them.

"Ordinarily, a breach is determined in reference to the 'reasonable person' standard of care. In other words, when a person fails to act as would a reasonable person under the same or similar circumstances, that person is said to have breached the applicable standard of care." *Davis v. Christian Broth. Homes of Jackson, Miss., Inc.*, 957 So.2d 390, 404 (Miss. App. 2007) (citing *Baker, Donelson, Bearman & Caldwell, P.C. v. Muirhead*, 920 So.2d 440, 449 (Miss. 2006)). **"Negligence is not presumed, rather it is presumed ordinary care has been used. The person charging negligence must show that the other party, by his act or omission, has violated some duty incumbent upon him and thereby caused the injury complained of."** *DeLaughter v. Womack*, 250 Miss. 190, 208 (Miss. 1964), overruled on other grounds.

The Plaintiff is required to offer proof on the breach of duty. *McIntosh v. Victoria Corporation*, 877 So.2d 519, 523 (Miss. Ct, App. 2004). She cannot "cannot sit back and produce no evidence" in support of their allegations. *Id.* at 522. In support of her allegations, the Plaintiff has

provided nothing more than mere conclusory statements that BSC was negligent, claiming that BSC is liable for her injuries simply because she was injured. The Plaintiff has not produced any evidence that would establish BSC acted unreasonably in any way in the manufacturing, design, labeling, packaging, or testing of the subject drug. Because the Plaintiff has not come forward with any evidence whatsoever to establish a breach of duty on behalf of BSC and because such a showing is essential to her negligence claim, BSC is also entitled to summary judgment as a matter of law with regard to the negligence claims.

C. ***The Plaintiff has not asserted a claim for violation of FDA regulations.***

Rule 8 of the *Federal Rules of Civil Procedure* requires that a plaintiff plead sufficient facts to put the defense on notice of the theories on which the complaint is based. *See* Fed.R.Civ.P. 8(d)(1); *see also TIG Ins. Co. v. Aon Re, Inc.*, 521 F.3d 351, 357 (5th Cir. 2008). It is clear that the original theory of Plaintiff's Complaint was that of a defective product as to its design, manufacture, labeling and/or marketing. *See Exhibit "A"*. Moreover, there was no mention of any FDA related claims by Plaintiff during the Case Management Conference, nor in her Initial Disclosures or discovery responses, served on June 16, 2008 and September 10, 2008, respectively. It was not until October 28, 2009, when Plaintiff for the first time propounded discovery in this matter, that Defendant was put on notice of Plaintiff's theory to pursue any FDA related claim.

There is nothing in the Plaintiff's Complaint to lead anyone to believe an FDA violation is a portion of her cause of action. Plaintiff has obviously recognized this flaw because she recently filed a separate lawsuit in this Court, styled *Jan Hughes vs. Boston Scientific Corporation*, Civil Action Number 2:09-cv-00001-KS-MTP, which specifically pleads a cause of action regarding alleged violations of FDA regulations. Because Plaintiff has not asserted a claim for a violation of FDA

regulations, any such claim made by Plaintiff in the instant matter should not be considered by this Court in ruling on the subject motion.

D. ***The Plaintiff has failed to establish a violation of FDA regulations.***

Should the Court allow Plaintiff to assert a cause of action regarding an alleged violation of FDA regulations, Plaintiff has wholly failed to offer any evidence in support of this claim, but merely appears to be asserting same because she recognizes the merit in Defendant's preemption defense. Specifically, Plaintiff has failed to offer any evidence that Defendant did not properly obtain or maintain its PMA. Indeed, it can not be denied that the FDA approved the HTA for sale after the entire PMA process was completed. Moreover, the PMA is still in effect today and no evidence has been presented that the FDA has pulled the Defendant's PMA regarding the HTA. Additionally, any alleged violation of FDA regulations by Defendant would be a claim better suited to be pursued by the FDA, not the Plaintiff.

In other pleadings in the instant matter, Plaintiff relies on this Court's holding in *Hearn v. Advanced Bionics, Corp*., 2008 WL 3896431 (S.D. Miss., Aug. 18, 2008) in support of her contention that she is entitled to discover whether or not Boston Scientific violated FDA regulations with regard to its PMA. In *Hearn*, the plaintiff was seeking damages for fraud against Advanced Bionics, Corp. after a claim was filed by the FDA against Advanced for alleged violations of FDA regulations. *Id.* at *1. Specifically, the Plaintiff in *Hearn* claimed that she relied on Advanced's misrepresentations regarding their approval status in settling her claim, to her detriment. *Id.* However, this matter is entirely distinguishable from the facts of *Hearn* in that the FDA has not filed a claim against Boston Scientific for any alleged violations. Plaintiff's interpretation of *Hearn* is far reaching and would open the door to all plaintiffs claiming FDA fraud to absolve themselves

from the doctrine of preemption. Plaintiff's contention that Defendant did not comply with FDA regulations is baseless and is nothing more than a "fishing exhibition" to create a claim to get around the doctrine of preemption. It is further important to point out that the Plaintiff has wholly failed to offer any explanation as to how an alleged violation during the PMA process caused any injury. Therefore, should this Court allow a claim in the instant matter for alleged violations of FDA regulations, Plaintiff has failed to offer any proof regarding these violations, nor has she shown how these alleged violations caused any injury. Accordingly, Plaintiff has failed to establish a violation of FDA regulations.

V. CONCLUSION

It is clear that Plaintiff's claims - strict liability, negligence and breach of warranty - are preempted by federal law. Because the HTA is a Class III product that has received and continues to maintain PMA, pursuant to *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, and other authority cited herein, none of the Plaintiff's claims survive the MDA's preemption clause. Further, to the extent that this Court could find that Plaintiff's claims are not preempted, Plaintiff has wholly failed to establish the essential elements of each cause of action. For the multitude of reasons set forth herein in great detail, Defendant should be dismissed as a matter of law.

WHEREFORE, PREMISES CONSIDERED, this Defendant requests that this Honorable Court grant its Motion for Summary Judgment. This Defendant would further request any additional relief this Court believes appropriate and/or necessary.

RESPECTFULLY SUBMITTED this, the 16th day of January, 2009.

BOSTON SCIENTIFIC CORPORATION

BY: **/s/ Leah N. Ledford**
LEAH N. LEDFORD, as One of Counsel of Record

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CERTIFICATE OF SERVICE

I, Leah N. Ledford, one of the counsel of record for Defendant, **BOSTON SCIENTIFIC CORPORATION,** do hereby certify that I have this date electronically filed the above and foregoing Memorandum Brief in Support of Motion for Summary Judgment with the Clerk of the Court using the ECF system which sent notification of such filing to the following

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